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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,055	09/16/2003	Yan Chang	GLYO-P02-007	5479

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BOSTON, MA 02110-2624

EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/665,055	Applicant(s) CHANG ET AL.	
	Examiner EVERETT WHITE	Art Unit 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>Sept. 16, 2003</u> . | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant method, Claims 1-3, 5, 12-18 and 20 fail to particularly point out the identity of the active agent (compound) to be administered (to be used) in the instantly claimed method. The current claim language is drawn to administering a compound which is not described structurally/formulaically/nomenclatorially; however, the active agent's (compound's) mode of action, function or effect requisite to practicing the claimed method is set forth. The claim is missing the critical element, which is the particular or distinct identity of the active agent (compound) to be used in the method claimed. It is noted that the claim is limited to what the administration or used of "a compound" is intended to accomplish rather than what the active agent actually represents as a chemical entity.

Regarding Claims 6-11 and 21 in the absence of the specific instructions intended to effectuate modification of pectin by the terms "modified", "pH modified", "thermally modified" and "enzymatically modified" or attachment to the chemical core claimed, the terms "modified", "pH modified", "thermally modified" and "enzymatically modified" render the claims in which they appear indefinite in all occurrences wherein Applicants fail to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties Applicants regard as those which will facilitate modification of pectin, requisite to identifying the composition of matter set forth in the claims.

In Claims 4 and 19, the metes and bound of the terms "substantially" and "interrupted" cannot be determined which renders the claims indefinite. Is "substantially" 20%, 49%, or 80%?

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In Claims 5 and 20, the term "side chains" have not been clearly defined. They end with a galactose or arabinose unit, but what exists between polymeric backbone and terminating galactose and arabinose? Is the group that exists between the polymeric backbone and terminating galactose and arabinose an alkyl moiety, polypeptide, or a polysaccharide?

In Claims 5 and 20, what is the identity of the polymeric backbone? In the absence of the specific polymeric backbone or distinct language to describe the polymeric backbone or the chemical name of the polymeric backbone of this invention, the identity of said polymeric backbone would be difficult to describe and the metes and bounds of said polymeric backbone that Applicants regard as the invention cannot be sufficiently determined because it has not been particularly pointed out or distinctly articulated in the claims.

### ***Double Patenting Provisional Statutory***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-10, 12-15, and 17-21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3, 5-10, 16-21, 23, 24, and 27-29 of copending Application No. 10/299,478. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Provisional Obviousness***

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 11 and 16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-15 and 31 of copending Application No. 10/299,478. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications set forth methods for controlling angiogenesis in an organism, which involves administering to said organism a therapeutically effective amount of a compound which binds to galectin, wherein the compound comprises a polymeric backbone which is a partially demethoxylated polygalacturonic acid interrupted with rhamnose residues. The inventions differ only in the range of the molecular weight of the compounds – Claim 11 of the instant application setting forth a molecular range of 1 to 150 kilodaltons, wherein Claims 12-15 and 31 of the '478 patent set forth compounds having molecular weights ranging from 1 to 60 kilodaltons. The instant invention set forth compounds having a molecular weight range that over-laps the molecular weight range of the compounds recited in the '478 patent. The claims of the '478 patent also does not claim administering the compound by inhalation. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicants invention having the '478 patent before him to replace the compounds thereof with substantially identical compounds in view of their closely related structures, similar molecular weights and the resulting expectation of similar angiogenic controlling properties.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **State of the Art**

The Raz et al patent (US Pat. No. 5,895,784), which discloses a method for treatment of cancer by oral administration of modified pectin, is cited to show the state of the art.

### **Summary**

3. All the claims are rejected.

### **Examiner's Telephone Number, Fax Number, and Other Information**

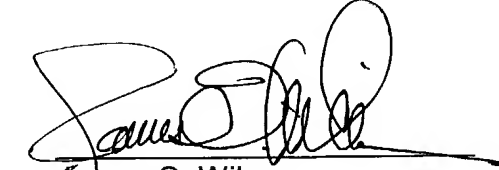
4. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
E.White

  
James O. Wilson  
Supervisory Primary Examiner  
Technology Center 1600